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8 UNITED STATES DISTRICT COURT
9 EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

10 YAKIMA VALLEY MEMORIAL
HOSPITAL, a Washington nonprofit
11 corporation,

12 Plaintiff,

13 v.

14 WASHINGTON STATE
DEPARTMENT OF HEALTH;
15 MARY C. SELECKY, in her official
capacity as Secretary of the
16 Washington State Department of
Health; and ROBERT M.
17 MCKENNA, in his official capacity
as Attorney General of the state of
18 Washington,

19 Defendants.
20

Case No.

COMPLAINT

21 Plaintiff, Yakima Valley Memorial Hospital ("Memorial"), brings this
22 action to promote competition in the market of providing elective angioplasty,
23 which is formally known as elective percutaneous coronary intervention ("PCI"),
24 to patients. Memorial seeks to create lower prices, improve patient care, and
25 increase access to this life-saving procedure for patients and consumers by
26 reforming inefficient and unlawful certificate of need ("CON") regulations that

1 permit a select number of hospitals to increase their profits at the expense of
2 individuals in need of the procedure.

3 As a community-focused, non-profit hospital, Memorial has served
4 the healthcare needs of patients for almost sixty years. As part of this commitment
5 to patient care, Memorial strives to provide innovative, life-saving treatments at
6 low costs to patients. One such treatment is the emergency PCI procedure, which
7 Memorial has offered since 2001 at a level of excellence and safety that
8 consistently surpasses the national quality standards for emergent PCIs. With
9 nearly a decade of emergency PCI experience, and two fully operational
10 angioplasty suites staffed with renowned cardiologists, Memorial will incur no
11 additional capital expense with the establishment of an elective PCI program.
12 Indeed, Memorial is ready, waiting, and eager for the opportunity to offer this
13 procedure to patients.

14 Despite Memorial's current ability to perform high quality and safe
15 elective PCI procedures, CON regulations of the Washington State Department of
16 Health ("DOH"), codified at WAC 246-310 et. seq. (the "regulations"), prevent
17 Memorial from offering this procedure. The regulations permit only a limited
18 number of hospitals in Washington State to perform elective PCI procedures,
19 which results in decreased patient access and increased costs to patients. The
20 specific sections which Memorial challenges are: 1) the "current capacity"
21 provisions of WAC 246-310-745, which award "forever franchises" to CON
22 approved hospitals, 2) the rounding methodology of WAC 246-310-745, which
23 determines need by using the highly unusual technique of rounding numbers down
24 instead of up (i.e. 1.916 is rounded to 1), and 3) the mandate that hospitals perform
25 a minimum of 300 PCIs per year to receive a CON, which is contrary to expert
26 consensus that has found 200 PCIs per year to be the appropriate standard

The beneficiaries of these highly restrictive, protectionist provisions include large New York Stock Exchange traded health care systems, like Health Management Associates, Inc., which owns Yakima Regional Medical and Cardiac Center and profits at the expense of community-based hospitals such as Memorial. Ironically, the same cardiologists that perform elective PCI procedures at Yakima Regional Medical and Cardiac Center can not perform the same elective procedure at Memorial. This is true despite the fact that Memorial currently has the necessary equipment and staff to provide high quality elective PCI procedures and safely performs those procedures for emergent cases.

The Department of Justice and the Federal Trade Commission have found that state certificate of need laws undercut consumer choice and weaken the market's ability to contain healthcare costs. Additionally, courts throughout the country have held that laws that restrict competition violate federal law when they fail to serve a clear state purpose and lack ongoing governmental supervision. Courts have also found that laws that burden the flow of commerce while having only illusory benefits to state residents are a violation of federal law. The elective PCI regulations that Memorial challenges have neither the purpose nor the effect of promoting access, quality of patient care, lower costs, or competition; therefore, they serve no clear state purpose, their claimed benefits are illusory, and they must be modified.

I. PARTIES

1. Memorial is a Washington nonprofit corporation having its principal place of business in Yakima, Washington.

2. Defendant DOH is an agency of the state of Washington. The DOH regulates elective PCI procedures through its certificate of need process.

3. Defendant Mary C. Selecky is the Secretary of the DOH. The DOH has enacted the challenged regulations and is responsible for their enforcement. This action is brought against Secretary Selecky in her official capacity

4. Defendant Robert M. McKenna is the Attorney General of the state of Washington. In that capacity, he "[c]onsults[s] with and advise[s] the several prosecuting attorneys in matters relating to the duties of their office, and when the interests of the state shall require, "he" attend[s] the trial of any person accused of a crime, and assist[s] in the prosecution." RCW 43.10.030(4). The Attorney General acts as general counsel of DOH. RCW 66.08.022. This action is brought against Attorney General McKenna in his official capacity.

II. JURISDICTION AND VENUE

5. This action arises under 15 U.S.C. §§ 15 and 26; 28 U.S.C. §§ 2201 and 2202; 42 U.S.C. §§ 1983 and 1988; and Article I, § 8, cl. 3 of the United States Constitution, commonly known as the Commerce Clause.

6. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331, 1337, 1367, 2201, and 2202.

7. Venue is proper in the Eastern District of Washington and in this division. Plaintiff does business in Yakima County and is primarily subject to enforcement in Yakima County.

II. FACTUAL BACKGROUND

8. Memorial is a non-profit hospital in Yakima, Washington.

9. DOH is a state agency that, among other things, regulates elective PCI procedures through its certificate of need regulations.

10. Memorial strives to provide Washington State patients and consumers with high quality medical services at low competitive prices.

1 11. The challenged regulations prevent Memorial from providing
2 elective PCI procedures to its patients even though it currently has the capability to
3 provide safe, affordable, and cost-effective elective PCI procedures. The
4 regulations include unnecessarily strict requirements under the guise of ensuring
5 patient care that in reality serve no purpose but to award monopolies to certain
6 hospitals in Washington, and burden the interstate commerce activities of entities
7 such as Memorial. In particular, Memorial challenges the following unlawful
8 regulations:

9 (a) Forever Franchise: The current rules define the "current
10 capacity" of a planning area to be the number of PCI procedures performed by
11 CON approved hospitals. WAC 246-310-745. This definition gives an unfair
12 "forever franchise" to approved providers, which guarantees them all of their
13 patient volume without considering whether they would be impacted by a proposed
14 new program. DOH has enacted this provision even though there is no evidence to
15 suggest that reallocating an existing provider's patient volume when it reaches a
16 certain level to another hospital would reduce quality. Instead of allowing existing
17 providers to "hoard" their entire patient volume, it is essential that some of the
18 volume be allocated back to the community for another provider. Not only would
19 this increase patient access, but it would generate lower costs by creating
20 competition. To further this goal, the regulations should mirror other Washington
21 State CON rules that prohibit the establishment of a new program only if it will
22 cause an existing provider to fall below the applicable minimum volume standard.

23 (b) Rounding: The regulations provide a need forecasting
24 methodology that utilizes an extraordinary rounding technique that drastically
25 underestimates the need for elective PCI procedures in planning areas. According
26 to WAC 246-310-745, a need of 1.916 rounds down to 1 program. The technique

1 of rounding fractions of .5 and above down to the lowest whole number goes
2 against common mathematical principles and serves no purpose but to
3 underestimate the need for PCI programs in Washington. The rounding
4 methodology that DOH has developed appears to be without precedent in
5 Washington State CON law.

6 (c) Minimum Volume: The rules arbitrarily restrict elective
7 PCIs to hospitals that can meet the 300 annual minimum volume requirement at
8 WAC 246-310-720. Setting the minimum volume amount at 300 is contrary to
9 consensus among experts in the field of cardiology that has found 200 to be the
10 appropriate minimum hospital volume. For example, the prestigious Johns
11 Hopkins C-PORT elective PCI study utilizes a minimum volume of two hundred
12 for hospital entry. Setting the minimum volume amount at 300 needlessly
13 prevents Memorial from performing elective PCI procedures even though it has the
14 capability to perform the procedures at the highest level of quality.

15 12. The challenged regulations burden Memorial's interstate
16 commerce activities including 1) providing elective PCI procedures to out-of-state
17 residents, 2) purchasing equipment and supplies for PCI procedures from outside
18 the state of Washington, and 3) recruiting physicians and staff from outside of
19 Washington State to perform PCI procedures.

20 13. The challenged regulations prevent both in-state entities that
21 own hospitals in Washington, and out-of-state entities that own or will potentially
22 own hospitals in Washington, from providing the procedure if they do not meet the
23 excessively strict requirements set forth in the regulations. These burdens on
24 commerce are excessive in relation to the illusory benefits of the PCI regulations.

25 14. Memorial notified the State defendants in October 2008 that
26 the challenged regulations, which were proposed rules at the time, were invalid and

1 sought their participation in changing them without litigation. The State
 2 defendants refused Memorial's requests and finalized the rules in December of
 3 2008. By refusing to alter the proposed rules, DOH's final elective PCI
 4 regulations violate federal law, and entrench the private hospital interests that were
 5 protected under the proposed rules.

6 15. The elective PCI regulations have a pernicious effect on
 7 competition and lack any redeeming virtue.

8 16. The state of Washington has no clearly articulated or
 9 affirmatively expressed policy of eliminating competition in the market of elective
 10 PCI procedures, and federal law and the Washington State Constitution expressly
 11 prohibits such limitations of competition.

12 17. Nothing in the regulations compels DOH to monitor market
 13 conditions or the competitiveness or reasonableness of prices for elective PCI
 14 procedures. Additionally, the state of Washington has not and does not plan to
 15 engage in any meaningful reexamination of the effect on competition of the
 16 challenged regulations. Having created these restraints on competition, DOH has
 17 failed to actively supervise the operation and effects of that regime.

18 18. The challenged regulations injure competition and consumers.
 19 Absent the challenged regulations, Memorial would be able to offer patients,
 20 consumers, and physicians greater selection and value, without offending any
 21 legitimate interests of the State in controlling the elective PCI market.

22 **FIRST CLAIM**

23 19. Plaintiff realleges and incorporates by reference, as if fully set
 24 forth herein, the allegations in paragraphs 1-18 above.

25 20. The challenged provisions are hybrid, per se unreasonable
 26 restraints of trade and are preempted by the federal Sherman Act 15 U.S.C. § 1.

1 The restraints of trade occur in interstate commerce and harm competition in the
2 market for PCI procedures. The harmful effect outweighs any benefit.

3 **SECOND CLAIM**

4 21. Plaintiff realleges and incorporates by reference, as if fully set
5 forth herein, the allegations in paragraphs 1-20 above.

6 22. WAC 246-310 et. seq. prohibit certain in-state entities that
7 own hospitals in Washington, such as Memorial, and out-of-state entities that own
8 or will potentially own hospitals in Washington from providing elective PCI
9 procedures. These burdens on commerce imposed by the elective PCI regulations
10 are excessive in relation to the regulations' putative local benefits and, therefore,
11 the regulations are in violation of Article I, § 8, cl. 3 of the United States
12 Constitution, known as the Dormant Commerce Clause.

13 23. Memorial has suffered an injury as a result of the violation and
14 it is likely that the injury will be redressed by a favorable decision.

15 **THIRD CLAIM**

16 24. Plaintiff realleges and incorporates by reference, as if fully set
17 forth herein, the allegations in paragraphs 1-23 above.

18 25. The challenged regulations deprive Memorial of rights,
19 privileges, and immunities secured by the Constitution and laws of the United
20 States. The challenged regulations thus constitute a deprivation of rights
21 actionable under 42 U.S.C. § 1983.

22 **III. RELIEF**

23 Plaintiff requests that the Court enter a judgment in plaintiff's favor
24 and against defendants:

25 A. Modifying WAC 246-310-745 so that the rule: 1) allows
26 reallocation of patient volume at CON approved hospitals back to the planning

1 area for proposed new programs, and 2) creates a "floor" that prevents the
2 establishment of a new program only if it would cause an existing provider in the
3 same planning area to fall below the minimum volume level.

4 B. Modifying WAC 246-310-745 so that the common
5 mathematical principles of rounding are used to determine need (i.e. 1.4 programs
6 would round down to 1 program. A need for 1.7 programs would round up to a
7 need for 2 programs);

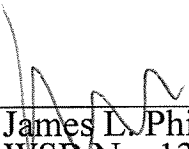
8 C. Modifying WAC 246-310-720(1) so that the hospital minimum
9 volume standard is changed to 200 per year;

10 D. Awarding plaintiff its costs and attorneys' fees; and

11 E. Granting such other relief as the Court deems just.

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13 DATED this 19th day of March, 2009.

14 MILLER NASH LLP

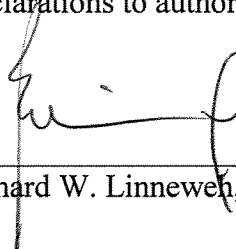
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VERIFICATION OF RICHARD W. LINNEWEH, JR.

I, Richard W. Linneweh, Jr., being duly sworn, hereby depose and say:

1. That I am over the age of eighteen and I believe in the obligations of an oath;
2. That I am President & CEO of Yakima Valley Memorial Hospital, Plaintiff in this action;
3. That my knowledge and representation of the facts alleged in the foregoing Complaint are based upon my personal knowledge, and are true and correct and accurate to the best of my knowledge, information and belief; and
4. That I submit this Complaint under oath and subject to the penalties applicable to perjury and sworn and unsworn declarations to authorities.



Richard W. Linneweh, Jr.

Dated: March 9, 2009

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